07-10-02

1644

CASE 4-30583A

FE 14
GND

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EL820015479US	July 9, 2002
Express Mail Label Number	Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

AMLOT ET AL.

APPLICATION NO: 09/770,002

FILED: JANUARY 25, 2001

Art Unit: 1644

FOR: USE OF CD25 BINDING MOLECULES IN THE TREATMENT OF RHEUMATOID ARTHRITIS OR SKIN DISEASES

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action mailed June 12, 2002 having a shortened one-month period for response which expires on July 12, 2002.

With respect to elected claims 4-6 and 8 (Group II), the Examiner has further required under 35 U.S.C. §121 that Applicants elect a specific disease and list all claims readable thereon including those subsequently added. Applicants provisionally elect, with traverse, the specific disease, rheumatoid arthritis for claims 4, 5 and 8. Applicants expressly reserve the right to file a divisional aplication directed to the non-elected species of claims 4, 5 and 8 in the event the Examiner's requirement for election of species is made final.

35 U.S.C.§ 121 maintains that for a proper requirement for restriction, the dual criteria of the statute must be met, that is, the application must contain two or more inventions which are both (1) "independent" and (2) "distinct" from one another. According to the U.S. Patent and Trademark Office's own definition, "independent" means "there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected in design, operation or effect..." [Emphasis added]. (Section 802.01 of the Manual of Patent Examining Procedure). The specification of the present application discloses a relationship and connection between rheumatoid arthritis, inflammatory diseases and hyperproliferative skin diseases. In particular, the CD25 binding molecule is required in the method of treatment of each of these diseases. Thus, the disease,

rheumatoid arthritis, recited in claims 4, 5 and 8 is related and connected to inflammatory diseases and hyperproliferative diseases recited in claims 4-6 and 8. Accordingly, the requirement for restriction and election is unwarranted under 35 U.S.C. §121 which, in order to authorize restriction, requires that the application claim "two or more independent and distinct inventions" [Emphasis added].

As a second ground for traversal, Applicants submit that the Examiner has failed to show that there would be a "serious burden" upon the Patent and Trademark Office to examine all of the pending claims. In this regard, MPEP §803, second paragraph, states:

"There must be a serious burden on the examiner if restriction is required."

It is respectfully submitted that since all of the diseases recited in claims 4-6 and 8 require the identical CD25 binding molecule, that a search and examination of inflammatory diseases and hyperproliferative diseases recited in claims 4-6 and 8 would substantially overlap with a search and examination of rheumatoid arthritis recited in claims 4, 5 and 8 and therefore would not impose a "serious burden" on the Examiner. In view of the above, withdrawal of the Restriction Requirement is respectfully requested. Applicants retain the right to petition from the Restriction Requirement under 37 C.F.R. §1.144.

Early and favorable action are respectfully requested.

Respectfully submitted,

Susan Hess

Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6938

Susan Hess
Attorney for Applicants
Reg. No. 37,350

Date: July 9, 2002